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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,865	02/07/2005	Hideko Kosaka	10921.0278USWO	1872

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HAMRE, SCHUMANN, MUELLER & LARSON, P.C.
P.O. BOX 2902
MINNEAPOLIS, MN 55402-0902

EXAMINER	
GERIDO, DWAN A	

ART UNIT	PAPER NUMBER
1797	

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10/01/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/523,865	KOSAKA, HIDEKO	
	Examiner	Art Unit	
	Dwan A. Gerido, Ph.D.	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 August 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7,8,13,18 and 19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 7, 8, 13, 18, 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application.
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1, 8, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Proffit et al., (US 2005/0106748).

4. Regarding claims 1, 8, and 13, Proffit et al., teach a method (examples 5 and 6), indicator (paragraph 0038), and test piece (paragraph 0027) for assaying albumin (paragraphs 0092, 0097) in a urine sample (paragraphs 0050, 0101). Proffit et al., do not explicitly teach measuring albumin with the claimed compounds; however, Proffit et al., do teach phloxine B which is identical to compounds (1)-1, (2)-1, and (3)-1 as a suitable indicator for the assay (paragraph 0038). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the teachings of Proffit et al., wherein phloxine B is used as an indicator determining albumin concentration in a urine sample as taught by Proffit et al.

5. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Proffit et al., (US 2005/0106748) in view of Lau (EP 0,361,244).

6. Regarding claim 7, Proffit et al., do not teach measuring an albumin concentration ranging from 10-20mg/dL.

Lau teaches a method of assaying urine albumin wherein the normal concentration of albumin ranges from 10-20 mg/dL (page 7 lines 48-54). Lau further teaches that protein concentrations below 10 mg/dL and above 20 mg/dL are indicative of a protein deficiency and/or disease states (page 7 lines 48-54). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Proffit et al., in view of Lau to measure albumin in the range of 10-20 mg/dL in order to determine whether a subject exhibits a normal albumin concentration in urine.

7. Claims 18 and 19 rejected under 35 U.S.C. 103(a) as being unpatentable over Proffit et al., (US 2005/0106748) in view of Albarella et al., (US 5,424,215).

8. Regarding claims 18 and 19, Proffit et al., do not teach a test piece comprising a sensitizer wherein the sensitizer is polyethylene glycol or polypropylene glycol.
Albarella et al., teach an assay for determination of albumin in a urine sample (column 1 lines 19-24) wherein a test strip contains polypropylene glycol as a sensitizer (column 2 lines 32-37, column 4 lines 1-27, table 1). Albarella et al., teach that it is advantageous to utilize a polycarbonate sensitizer as a means of lowering initial reactivity of a reagent paper, and for decreasing false positive readings for protein concentration (column 1 lines 45-50). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Proffit et al., in view of Albarella et al., to utilize polypropylene glycol as a sensitizer in

order to reduce reactivity of a reagent paper, and to decrease false positives as taught by Albarella et al.

Response to Arguments

9. Applicant's arguments filed August 6, 2010 have been fully considered but they are not persuasive.

10. Applicant has amended the claims to recite a method, indicator, and test piece for assaying albumin in a urine sample wherein the albumin is assayed in a solution have a pH equal to or below the pKa of the indicator, and wherein the solution is colorless to light orange without albumin and red to purple with albumin, and argues that the amended claims are not taught by reference to Proffit et al. The Examiner respectfully disagrees. Applicant first argues that reference to Proffit et al., is directed to a method of enhancing transolubility of organic acid reagents and is silent to assaying albumin in urine. The Examiner agrees that Proffit et al., teach enhancing transolubility or organic acid reagents as this is clearly stated in the title of Proffit et al., but the Examiner disagrees with Applicants assertion that Proffit et al., does not teach assaying urinary albumin. Specifically, the Examiner points to paragraphs 0002, 0004, 0050, and 0101 all of which clearly show that the teachings of Proffit et al., can be utilized with urine samples. Given the fact that the indicator reacts with albumin, one would expect that the teachings of Proffit et al., can be utilized to assay urinary albumin. With respect to the change in color (of the indicator), absent any indication that the change in color is specific and/or unique to the instant invention, the Examiner is interpreting the color change as an inherent property of the indicator.

Next, Applicant argues that Proffit et al., only teach pyrogallol red dye as an indicator for detecting protein. Here the Examiner points to paragraph 0038 of Proffit et al., which lists several dyes/indicators that can be utilized in the teachings of Proffit et al., of which phloxine B (identical to claimed compounds) is one of the choices. At no point does Proffit et al., recite specific dyes/indicators utilized with specific samples and/or analytes thus one would expect phloxine B to act as a suitable indicator for urinary albumin.

Applicant also argues that Proffit et al., do not teach assaying albumin in a solution having a pH equal to or below the pKa of the indicator. At paragraphs 0013 and 0014 of the instant specification, the pH range is recited as being between 1.5 and 4.5 with 2.0 to 3.5 being the preferred range. Proffit et al., teach the claimed pH range at paragraphs 0092 and 0097, both of which recite a buffer having a pH of 2.5 which is clearly within the pH range of the instant specification.

With respect to Applicants arguments regarding the concentration of albumin in a urine sample, the Examiner notes that the claimed concentration range is listed in dependent claim 7 and not any of the independent claims. The Examiner concedes that Proffit et al., do not teach albumin concentration ranging from 10 to 20mg/dL, however Proffit et al., has been modified with reference to Lau which teaches assaying urinary albumin wherein the normal concentration range is between 10 to 20mg/dL. Lau teaches that concentrations below 10mg/dL and above 20mg/dL are indicators for disease states thereby providing sufficient motivation to combine the references.

Finally, while reference to Proffit et al., may not explicitly teach the mechanism by which phloxine B reacts when utilized to detect urinary albumin, it is the Examiners opinion that Proffit

et al., does teach the conditions set forth by the instant claims in a manner that would render the instant invention obvious to one of ordinary skill in the art. Therefore, given the teaching of the prior art, and the arguments presented here, the rejection of claims 1, 7, 8, 13, 18, and 19 are maintained.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwan A. Gerido, Ph.D. whose telephone number is (571)270-3714. The examiner can normally be reached on Monday - Friday, 9:00 - 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571) 272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DAG

/ROBERT J. HILL, JR/
Primary Examiner, Art Unit 1797